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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,804	03/25/2002	Jean-Claude Madelmont	ADIR 366 PCT	8809

25666 7590 07/24/2003

THE FIRM OF HUESCHEN AND SAGE  
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KALAMAZOO, MI 49007

EXAMINER
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KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/019,804

Applicant(s)

MADELMONT ET AL.

Examiner

Bruck Kifle, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,21,26, and 34-36 is/are rejected.
- 7) ☐ Claim(s) 27,37 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 20 and 21(in part), 22, 29 and 36-38 (in part), drawn to a compound of formula Ia<sub>1</sub>, process of preparing and the pharmaceutical composition.

Group II, claims 20 and 21 (in part), 23, 24, 30, 31 and 36-38 (in part), drawn to a compound of formula Ia<sub>2</sub> and Ia<sub>3</sub> process of preparing and the pharmaceutical composition.

Group III, claims 20 and 21 (in part), 25, 32 and 36-38 (in part), drawn to a compound of formula Ia<sub>4</sub>, process of preparing and the pharmaceutical composition.

Group IV, claims 20 and 21 (in part), 26, 27, 34, 35 and 36-38 (in part), drawn to a compound of formula Ib<sub>1</sub> and Ib<sub>2</sub> process of preparing and the pharmaceutical composition.

Group V, claims 20 and 21 (in part), 28, 33 and 36-38 (in part), drawn to a compound of formula Ia<sub>5</sub>, process of preparing and the pharmaceutical composition.

Group VI, claims 20, 21 and 36-38 (in part), drawn to a compound of formula Ia, not covered by groups I-V above, but generically embraced by the claims, process of preparing and their pharmaceutical composition. Should Applicants elect this group, election of a specific "M" is required.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: The claims lack unity of invention because compounds of formula (Ia) and (Ib) do not possess single structural element that is shared by all of the alternatives. The common structural feature shared by all of the alternatives of formula (Ia) and (Ib), namely the quaternary nitrogen ion, is old. This common structural feature is **not** a patentable advance over the prior art.

The claims are drawn to structurally dissimilar compounds which are classified separately, require separate literature searches and are not art recognized equivalents. They are made and used independently.

Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d). The compounds of formula (Ia) or (Ib) are not so linked as to form a single inventive concept. The compounds are so diverse in scope that a prior art anticipating one compound under 35 USC 102 would not render obvious another compound of the same claim under 35 USC 103.

During a telephone conversation with Mr. Patrick Sage on July 23, 2003 a provisional election was made with traverse to prosecute the invention of group IV, claims 20 and 21 (in part), 26, 27, 34, 35 and 36-38 (in part), drawn to a compound of formula Ib<sub>1</sub> and Ib<sub>2</sub> process of preparing and the pharmaceutical composition. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-25, 28-33 and subject matter not falling under elected group IV of claims 20, 21 and 36-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 21, 26 and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Reymond et al. (Helvicta Chimica Acta – Vol. 79 (1996), 1651-1669). The compound of claim 26 reads on the compound N-MePiH<sup>+</sup> (see page 1654). Note the counter ion for this compound is chloride which comes from the lithium chloride in solution (see last paragraph on the bottom of page 1652).

Claims 37 and 38 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 36. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 703-305-4484. The examiner can normally be reached on 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Bruck Kifle, Ph.D.  
Primary Examiner  
Art Unit 1624

BK  
July 23, 2003